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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/722,777	11/26/2003	Robert J. Marshall	PRL-101	7232
51079	7590	02/02/2010	EXAMINER	
AMIN Talati, LLC			UNDERDAHL, THANE E	
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SUITE 400			ART UNIT	PAPER NUMBER
CHICAGO, IL 60654			1651	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/722,777	MARSHALL, ROBERT J.	
	Examiner	Art Unit	
	THANE UNDERDAHL	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 10 November 2009.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 4-22 and 24-38 is/are pending in the application.
 4a) Of the above claim(s) 13-19 is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 4-12,20-22 and 24-38 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11/10/09</u> . | 6) <input type="checkbox"/> Other: _____ . |

Detailed Action

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/10/09 has been entered.

Claims 4-22, and 24-38 are pending. Claims 13-19 are withdrawn. Claims 1-3 and 23 are cancelled. Claims 4-8, 10, 12, 20, 21, and 24 have been amended. Claims 25-38 are new. Claims 4-12, 20-22, 24-38 are considered in this Office Action.

Response to Applicant's Arguments

In the response submitted by the Applicant the following 35 U.S.C § 103 (a) rejections are withdrawn:

- Claims 4-10 and 20-22 as being unpatentable over Hastings et al. (U.S. Patent # 6368617) in view of Hermann et al. (European Journal of Pharmaceutical Sciences, 1996) with additional support provided by Pyruvate Dehydrogenase & Krebs Cycle (1998) and Reed (JBC, 2001)
- Claims 11 and 12 remain rejected and new claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hastings et al. and Hermann et al. as applied to the rejections of claims 4-10 and 20-22 above and in further view of Reddy et al. (U.S. Patent # 6,080,401)

The Applicant's amendments limiting that the composition now has **dihydrolipoic acid (DHLA)** as a component rather than an intended result and the addition of "an agent which halts probiotic activity" necessitated the above withdrawal. Also the 35 U.S.C § 112 rejection of claim 4-12, 20-22 and 24 is withdrawn in light of the Applicant's amendment removing the term "harvestable quantity".

Interpretation of the Claims

The newly amended claims while not indefinite have language that is broader than the Applicant may have intended or are product by process limitations which are provided little patentable weight. In the instant case the term "naturally-derived" DHLA is given little patentable weight since this is a product by process limitation concerning how the DHLA was made. M.P.E.P. § 2113 state "Product by process claims are not limited to the manipulations of the recited steps, only the structure implied by the steps". Therefore the product being examined in the claims includes DHLA and not the steps used to obtain it, since the chemical structure would be the same regardless of source. This is applied to claim 29 as well, since it only recites the method of obtaining the DHLA. Since the claims are to a composition and not a method, such product by process limitations are not limiting.

Also the Applicant has included a series of intended results or intended uses for their composition. These include that the composition is a "microbial culture medium" or the composition is a "broth acting as a microbial culture medium" or "is used in a medicament or nutritional supplement". However these claims are to a composition as such are defined by their components (M.P.E.P. § 2111.02). Therefore art reading components will meet the limitations concerning the intended uses or results since the physical makeup of the solutions taught in the art are the same.

Claim 24 includes the limitation that the composition is "consisting essentially of" a series of components. M.P.E.P. § 2111.03 clearly indicates that the transitional phrase "consisting essentially of" limits the scope of a claim to the specified materials or steps "and those that do not materially affect the basic and novel characteristic(s)" of

the claimed invention. *In re Herz*, 537 F.2d 549, 551-52, 190 USPQ 461, 463 (CCPA 1976) (emphasis in original). “A ‘consisting essentially of’ claim occupies a middle ground between closed claims that are written in a ‘consisting of’ format and fully open claims that are drafted in a ‘comprising’ format.” *PPG Industries v. Guardian Industries*, 156 F.3d 1351, 1354, 48 USPQ2d 1351, 1353-54 (Fed. Cir. 1998), *et al.* For the purposes of searching for and applying prior art under 35 U.S.C. § 102 and 103, *absent a clear indication in the specification or claims of what the basic and novel characteristics actually are*, “consisting essentially of” will be construed as equivalent to “comprising.” If an applicant contends the materials in the prior art are excluded by the recitation of “consisting essentially of,” applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant’s invention. *In re De Lajarte*, 337 F.2d 870, 143 USPQ 256 (CCPA 1964) *et al.* Since the specification in this case does not particularly point out the basic and novel characteristics of the claimed composition, “consisting essentially of” in claim 24 has been interpreted as “comprising” for the purpose of art rejections.

Response to the 132 Declarations

The Examiner has considered the Declaration by Mr. Robert J. Marshall filed 8/14/09.

1. Mr. Marshall notes a series of statements (paragraph 7) from previous office actions but does not follow up with arguments to their inaccuracy or how they do not apply to the current claims.

2. Mr. Marshall argues that the addition of an agent to halt probiotic activity is outside the scope of the teachings of Hastings et al. and Reddy et al (paragraph 9). The Examiner agrees and has withdrawn this rejection.
3. Mr. Marshal argues that the temperature the claimed composition is critical (paragraphs 10, 12-14). However this argument is outside the scope of the claims since temperature is not a limitation at this time.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 4-10, 20-22, 25-27, and 29-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hastings et al. (U.S. Patent # 6368617, April 9, 2002) in view of Niggemann (DE 19730538, 1999), Biewenga et al. (Gen. Pharmac, 1997) and in further of Hermann et al. (Euro. J. Pharm Sci, 1996) in light of support by Dunne et al. and Mercenier et al.

These claims are to a composition comprising the following:

- A least one probiotic organism
- R-lipoic acid
- One nutritive agent

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- DHLA
- An agent which halts probiotic activity such as ethanol

The probiotic organism can be from *Lactobacillus*, *Bifidobacterium*, *Enterococcus*, *Streptococcus thermophilus*. More specifically the microorganisms can be selected from the group consisting of: *L. acidophilus*, *L. paracasei*, *L. fermentum*, *L. rhamnosus*, *L. johnsonii*, *L. plantarum*, *L. reuteri*, *L. salivarius*, *L. brevis*, *L. bulgaricus*, *L. helveticus*, *L. grasserri*, *L. casei*, *L. lactis*, *B. bifidum*, *B. breve*, *B. infantis*, *B. longum*, *B. lactis*, *E. faecium*, and *E. faecalis*.

Claim 21 is an additional composition comprising *B. longum*, *L. acidophilus*, *E. faecium*, *Streptococcus thermophilus* and R-Lipoic acid, DHLA and at least one nutritive agent. Claim 22 depends from claim 21 and further comprises *B. breve*, *B. infantis*, *L. casei*, *L. fermentum*, *L. helveticus*, and *L. plantarum*.

Hastings et al. teach a composition in claim 11 (col 7) comprising a probiotic blend of *B. bifidum* and *L. acidophilus*, a nutrient substance such as omega-3 fatty acids and saccharides, and can further comprise alpha-lipoic acid as an antioxidant (claim 15, col 8). This composition can be formulated into a liquid broth (Example 1). While Hastings does not teach solely the (R) enantiomer of lipoic acid, it is obvious to use this enantiomer from the teachings of Hermann et al.

Herman et al. teach that of the racemic forms of alpha lipoic acid, the (R) enantiomer has greater bioavailability than the (S) enantiomer (Abstract, last 3 lines). One of ordinary skill in the art that knew of the teachings of Hermann et al. would recognize using the enantiomerically pure (R) form of lipoic acid would improve the

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composition of Hastings et al. The motivation is provided by Hastings et al. who show that the bioavailability of R-lipoic acid is superior to S-lipoic acid. The reasonable expectation of success is provided by Hastings et al. who show that the composition which already includes R-lipoic in a racemic mix with S-lipoic acid can be formulated.

While it would be obvious to use R-lipoic acid as antioxidant, Hastings et al. does not teach adding DHLA, which is the reduced form of R-lipoic acid. However this would be obvious to one of ordinary skill in the art in view of the teachings of Biewenga et al. They teach that DHLA and lipoic acid are both antioxidants and that DHLA even has more antioxidant properties than lipoic acid (Biewenga, See Abstract). Therefore Biewenga et al. establishes DHLA and lipoic acid as art recognized equivalents for the same purpose and as such it would be obvious to combine the two in the same composition (M.P.E.P. § 2144.06 I)

Hastings et al. also does not teach a composition containing all the bacteria listed in claims 21 or 22. However these bacteria are well known in the art as probiotic bacteria as supported by Mercenier et al. (Current Pharm. Design Jan. 2003) and Dunne et al. (Antonie van Leeuwnhoek, 1999). Hastings et al. already uses a probiotic blend of *B. bifidum* and *L. acidophilus*. According to M.P.E.P. § 2144.06:

“It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art.”

Since Hastings et al. already adds a probiotic blend to their composition it would be *prima facia* obvious to add other probiotic organisms to their invention.

Hastings et al. does not teach adding an agent that halts probiotic activity such as ethanol. However this would be obvious in view of Niggemann. They teach that small amounts of ethanol are frequently added to other probiotic compositions such as kefir and kombucha (Niggemann, pg 3 of translation). They teach that these small amounts of ethanol increase the shelf life of probiotic products (Niggemann, pg 2 of translation). Niggemann et al. even teaches that these probiotic compositions are beneficial to the intestine (Niggemann, pg 1 of translation, bottom) like those of Hastings et al. It would be obvious for one of ordinary skill in the art to apply the teachings of Niggemann to those of Hastings since Niggemann expressly teach that small amounts of ethanol improve the shelf life of probiotic products and are still beneficial to the intestine. This would simply be a matter of using a known technique to improve other probiotic compositions ((KSR Int'l Co. v. Teleflex, Inc. 550 U.S. 398 (2007), pg 13).

Therefore claims 4-10, 20-22, 25-27, and 29-35 are obvious in view of the above references.

Claims 4-12, 20-22, and 24-38 rejected under 35 U.S.C. 103(a) as being unpatentable over Hastings et al., Niggemann, Biewenga et al. and Hermann et al. (Euro. J. Pharm Sci, 1996) in light of support by Dunne et al. and Mercenier et al. as applied to claims above, and further in view of Reddy et al. (U.S. Patent # 6080401, 2000)

The descriptions of claims 4-10, 20-22, 25-27, and 29-35 are recited in the 35 U.S.C § 103 rejection above and are applied here as well. Claims 11, 12, 24, 28, 36-38

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add the herb turmeric rhizome (aka. *curcuma longa* or Haridra) which is not taught by Hastings et al. and the above references. Regardless this would be obvious in view of the teachings of Reddy et al.

Claim 24 adds the product by process limitation that the “broth acting as a microbial culture media producing naturally-derived dihydrolipoic acid”. As stated above the claim is to a composition so method steps or intended results are given little patentable weight over art that already reads on the ingredients of the composition (see M.P.E.P. § 2111.02 and 2113).

As mentioned in the reference above, Hastings et al. in view of the other references listed above renders obvious a composition that comprises at least one live probiotic organism, R-lipoic acid, DHLA, a nutritive agent and an agent to halt probiotic activity such as ethanol. However these two references do not specifically teach the addition of *curcuma longa* to their composition. This is taught by Reddy et al.

Reddy et al. teach a composition that, like Hastings et al., includes a probiotic blend of *Bifidobacterium* and *Lactobacillus* (Col 9, lines 33-44) to assist in weight loss and dieting (col 4, line 12), which is the same reason as Hastings et al. Reddy et al. also adds *Curcuma longa* to the composition (col 8, line 5) as a hepatic stimulant in a range of 10 to 100 mg per dose (Table 11). It would have been obvious to someone skilled in the art to add *Curcuma longa* to the composition of Hastings et al. since both inventions share a common goal for a composition to assist in a diet and also share common materials such as a probiotic blend (see M.P.E.P. § 2144.06).

While the art above teaches the components of the composition of claim 4 they do not teach the amounts limited by claim 12. However, M.P.E.P. § 2144.05 II states:

Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical.

Absent any teaching of criticality by the applicant concerning the amounts listed in claim 12 for the composition of claim 4, it would be *prima facie* obvious that one of ordinary skill in the art would recognize that the amounts listed in claim 12 are result effective variables whose ratio and concentration are a matter of routine optimization. This rejection can be overcome with evidence of unexpected results that are commensurate with the scope of the claim for these concentrations.

Therefore claims 4-12, 20-22, and 24-38 are obvious in view of the above references.

In summary no claims, as written, are allowed for this application.

In response to this office action the applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP § 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 U.S.C. § 102 or 35 U.S.C. § 103(a) once the aforementioned issue(s) is/are addressed.

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Applicant is requested to provide a list of all copending U.S. applications that set forth similar subject matter to the present claims. A copy of such copending claims is requested in response to this Office action.

CONTACT INFORMATION

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thane Underdahl whose telephone number is (571) 272-9042. The examiner can normally be reached Monday through Thursday, 8:00 to 17:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached at (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Thane Underdahl
Art Unit 1651

/Leon B Lankford/
Primary Examiner, Art Unit 1651